UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,738	09/15/2005	Steffen Goletz	08358.0006	1565

22852 7590 08/10/2007

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
AEDER, SEAN E	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
08/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,738	GOLETZ ET AL.	
	Examiner	Art Unit	
	Sean E. Aeder	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

The Amendments and Remarks filed 6/14/07 in response to the Office Action of 12/14/06 are acknowledged and have been entered.

All previous claims have been cancelled by Applicant

Claims 50-80 have been added by Applicant.

Claims 50-80 are pending and are currently under examination.

The following Office Action contains NEW rejections.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 75-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 75-78 are rejected for reciting: "the subject to be treated". There is insufficient antecedent basis for this limitation in the claims. The claims from which claims 75-78 depend do not recite any subjects to be treated.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 53-78 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The invention appears to employ novel biological materials, specifically NM-F9 and NM-D4 tumor cells. Since the biological materials are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological materials are not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit of the biological materials. The specification does not disclose a repeatable process to obtain the biological materials and it is not apparent if the biological materials are readily available to the public. It is noted that Applicant has deposited the biological materials (Deposit Declaration submitted 6/14/07), but there is no indication in the specification as to public availability. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of the deposit will be made (see 37 C.F.R. 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Applicant's attention is directed to M.P.E.P. 2400 in general, and specifically to 2411.05, as well as 37 C.F.R. 1.809(d), wherein it is set forth that the "specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." The specification should be amended to include this information, however, Applicant is cautioned to avoid the entry of new matter into the specification by adding any other information. Finally, Applicant is advised that the address for the ATCC has recently changed, and that the new address should appear in the specification. The new address is:

American Type Culture Collection

10801 University Boulevard

Manassas, VA 20110-2209

It is noted that the Response of 6/14/07 states that Applicant has attached and executed Deposit Declaration and that Applicant has amended the specification to include the date of deposits and the accession numbers for the deposited cells.

The Deposit Declaration and the amendments to the specification have been carefully considered, but would not overcome this rejection. As stated above, if the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. To obviate this rejection, it is suggested Applicant submit an affidavit or declaration or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 51, 52, 54-62, and 67-80 are rejected under 35 U.S.C. 102(e) as being anticipated by Subjeck et al (US Patent 6,984,384 B1; filed 9/29/00).

The claims are drawn to lysates obtainable by subjecting tumor cells to various temperatures for various periods of time. The claims are further drawn to dendritic cells loaded with said lysates.

Subjeck et al teaches a lysate of mutated tumor cells derived from a patient and a composition of said lysate obtainable by a process comprising the steps of: (a) inducing necrosis of tumor cells by subjecting the cells to a temperature of 43C for two hours; and (b) lysing said necrotic tumor cells (see column 19, in particular). It is noted that the instant claims describing lysate as a "pharmaceutical composition" or a "vaccine composition" are merely describing an intended use of the claimed lysate compositions. It is noted that statements of intended purposes or uses are not considered limitations because they merely state an intended use of the invention rather than any distinct definition of any of the claimed invention's limitations (see Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)). Recitation of statements describing the claimed product as a medicament intended to treat a condition are not given patentable weight and are not limitations to the claims. The relationships recited in claims 75-80 would be attributed to the tumor cells taught by Subjeck under different circumstances. Although Subjeck et al does not specifically

teach the percentage of the tumor cells are necrotic after induction of necrosis, the claimed product appear to be the same as the prior art, absent a showing of unobvious differences. Further, although claims 51, 67, and 68 recite that the claimed products are obtainable by subjecting cells to a temperature of more than 41.2C for more than 2 hours (note that Subjeck et al teaches subjecting cells to a temperature of more than 41.2C for 2 hours), this limitation is a product by process claim and as such the method in which the product is obtained is immaterial to their patentability. From the data provided in the instant specification (see pages 42-43, in particular), one of skill in the art would expect the product produced by the method taught by Subjeck et al to be patentably identical to the products recited in the claims. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product I in the product-by-process claim I is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re* Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). See also MPEP 2113. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the products produced by the method of the prior art do not possess the same material and structural characteristics of the claimed products. In the absence of evidence to the contrary, the burden is on Applicant to prove that the claimed products are different from that taught by the prior art and to establish patentable differences. See In re Best 562F .2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2nd 1992 (PTO Bd. Pat. App.

& Int. 1989). Subjeck et al further teaches compositions comprising immature and mature dendritic cells loaded with the lysate of mutated tumor cells derived from a patient obtainable by a process comprising the steps of: (a) inducing necrosis of tumor cells by subjecting the cells to a temperature of 43C for two hours; and (b) lysing said necrotic tumor cells (columns 26-27, in particular). Subjeck et al further teaches comprising immature and mature dendritic cells loaded with the lysate of mutated tumor cells combined with an adjuvant (column 23, in particular).

Claims 50-52, 55, 57, 61, 63, 65, 67, 69, 71, 73, and 75-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Samali et al (FEBS letters, November 1999, 461(3):306-310).

The claims are drawn to lysates obtainable by subjecting tumor cells to various temperatures for various periods of time.

Samali et al teaches a lysate obtained by a process comprising the steps of inducing necrosis of tumor cells by subjecting cells to a temperature of at least 45.5C to 47C for at least 15 minutes and lysing said necrotic cells so as to obtain a lysate (pages 307-308, in particular). Further, although claims 51, 67, and 68 recite that the claimed products are obtainable by subjecting cells to a temperature of more than 41.2C for more than 2 hours (note that Samali et al teaches subjecting cells to a temperature of 46C for 1 hour, see pages 307-308 of Samali et al), this limitation is a product by process claim and as such the method in which the product is obtained is immaterial to their patentability. From the data provided in the instant specification (see pages 42-43,

in particular), one of skill in the art would expect the product produced by the method taught by Samali et al to be patentably identical to the products recited in the claims. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product I in the product-by-process claim I is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re* Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). See also MPEP 2113. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the products produced by the method of the prior art do not possess the same material and structural characteristics of the claimed products. In the absence of evidence to the contrary, the burden is on Applicant to prove that the claimed products are different from that taught by the prior art and to establish patentable differences. See In re Best 562F .2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2nd 1992 (PTO Bd. Pat. App. & Int. 1989). Samali et al further teaches lysates where ore than 70% of the tumor cells are necrotic after induction of necrosis (see Figure 2, in particular). Further, Apoptotic cell death of the tumor cells would result in mutation (see Figure 2).

Summary

No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA
/Misook Yu/ Misook Yu
Primary Examiner, Art Unit 1642